### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JOHN LYON, Individually	and on Behalf of All
Others Similarly Situated,	

Case No. \_\_\_\_\_

Plaintiff,

**CLASS ACTION** 

v.

TG THERAPEUTICS, INC., MICHAEL S. WEISS, SEAN A. POWER, and ROBERT NIECESTRO,

Defendants.

JURY TRIAL DEMANDED

#### COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff John Lyon ("Plaintiff"), by his attorneys, except for his own acts, which are based on knowledge, alleges the following based upon the investigation of counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by TG Therapeutics, Inc. ("TG Therapeutics" or the "Company"), as well as regulatory filings and reports, securities analyst reports and advisories by the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

- 2. TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the Company is developing two therapies targeting hematological malignancies and autoimmune diseases: (i) TG-1101 (ublituximab), a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and (ii) TGR-1202, an orally available PI3K delta inhibitor for various hematologic malignancies.
- 3. On September 17, 2015, the Company announced that it had reached an agreement with the U.S. Food and Drug Administration ("FDA") regarding a Special Protocol Assessment ("SPA") on the design of a Phase 3 clinical trial for its proprietary combination of TG-1101 (ublituximab), its glycoengineered anti-CD20 monoclonal antibody, plus TGR-1202, the Company's once-daily PI3K-delta inhibitor, for the treatment of Chronic Lymphocytic Leukemia ("CLL"). The Phase 3 clinical trial, referred to by the Company as "GENUINE," consisted of two parts:
  - Part I to evaluate the effect of the addition of TG-1101 to ibrutinib on overall response rate (ORR) in approximately the first 200 patients enrolled, to support a filing for accelerated approval of TG-1101; and
  - Part II to evaluate the effect of the addition of TG-1101 to ibrutinib on progression-free survival (PFS) in all study patients (approximately 330), to support a filing for full approval of TG-1101.
- 4. The purpose of the Phase III GENUINE trial was to show that TG-1101, in combination with Imbruvica (the trade name for an ibrutinib-based small molecule drug used to treat B cell cancers), could show an improvement in overall response rate ("ORR") and progression-free survival ("PFS") in 330 previously-treated patient with certain cancer cell mutations.

- 5. Throughout the Class Period, the Defendants named herein materially misrepresented and/or omitted material information concerning the GENUINE Phase III trial, assuring investors it was a "best-in-class treatment" that would be "successful" and "offer patients a novel chemo-free treatment option."
- 6. On October 13, 2016, TG Therapeutics announced that the Company had filed an "amended protocol for its GENUINE Phase 3 trial," which entirely abandoned Part II of the Phase III GENUINE study designed to measure the combination's effect on progression-free survival, thereby annulling the SPA with the FDA. Accordingly, the study's sole primary endpoint was reduced to only overall response rate (ORR), as contemplated in Part I of the study, and the target enrollment was reduced to only 120 patients. As a result of cutting enrollment by more than half, the Company stated it could be another two years to reach 330 patients the number needed to have sufficient powering to show a PFS benefit.
- 7. According to analysts, excluding patients who have already taken Imbruvica "is an obvious barrier to enrollment" and significantly increases the likelihood that the FDA will not approve the combination treatment.
- 8. Upon the news, TG Therapeutics' stock declined \$2.24 per share from \$8.25 per share on October 12, 2016 to \$6.01 on October 17, 2016, or 27%.
- 9. As a result of the fraudulent conduct alleged herein, Plaintiff and other members of the Class purchased TG Therapeutics securities at artificially inflated prices and suffered significant losses and damages once the truth emerged.

#### **JURISDICTION AND VENUE**

10. The federal law claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated

thereunder by the SEC (17 C.F.R. § 240.10b-5).

- 11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Securities Act (15 U.S.C. §78aa.). This Court has jurisdiction over each Defendant named herein because each Defendant is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.
- 12. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of material false and/or misleading information, occurred in this District. TG Therapeutics is headquartered in this District, with its principal place of business located at 2 Gansevoort Street, 9th Floor, New York, NY 10014.

#### **PARTIES**

- 13. Plaintiff John Lyon purchased TG Therapeutics securities within the Class Period and, as a result, was damaged thereby. Plaintiff's certification evidencing his transactions is attached hereto as Exhibit A.
- 14. Defendant TG Therapeutics is a New York corporation with its principal executive offices located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. TG Therapeutics' common stock trades on the NASDAQ under the ticker symbol "TGTX."
- 15. Defendant Michael S. Weiss ("Weiss") has been the Company's Chief Executive Officer ("CEO"), Interim President and Executive Chairman since December 2011.
- 16. Defendant Sean A. Power ("Power") has been the Company's Chief Financial Officer since December 2011.

- 17. Defendant Robert Niecestro ("Niecestro") has been the Company's Executive Vice President of Clinical and Regulatory since December 2011.
- 18. Defendants in Paragraphs 15-17 are collectively referred to herein as the "Individual Defendants."
  - 19. Each of the Individual Defendants:
    - (a) directly participated in the management of the Company;
    - (b) was directly involved in the day-to-day operations of the Company at the highest levels;
    - (c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
    - (d) was directly or indirectly involved in the oversight or implementation of theCompany's internal controls;
    - (e) was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
    - (f) approved or ratified these statements in violation of the federal securities laws.
- 20. Because of the Individual Defendants' positions within the Company, they had access to undisclosed information about TG Therapeutics' business, operations, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and

employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

- 21. As officers of a publicly-held company whose securities were, and are, registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.
- the power and authority to control the contents of TG Therapeutics' reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information; the result of the collective actions of the Individual Defendants.

23. Each of the Individual Defendants are liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of TG Therapeutics securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding TG Therapeutics' business, operations, management and the intrinsic value of its securities and (ii) caused Plaintiff and other shareholders to purchase TG Therapeutics securities at artificially inflated prices.

#### SUBSTANTIVE ALLEGATIONS

#### A. Company Background

- 24. TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. B-cell malignancies represent a diverse collection of diseases, including most non-Hodgkin's lymphomas (NHL), some leukaemias, and myelomas.
- 25. The Company's lead product under development is TG-1101, an antibody for the treatment of B-cell hematologic malignancies. Hematologic malignancies includes cancers derived from the bone marrow and lymph tissue. The non-Hodgkin's lymphomas (NHL) represent a heterogeneous subset of these malignancies, which, in the United States, is about 4-5% of all new cancer cases, and is the eighth leading cause of cancer death.
- 26. TG-1101 targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. TG Therapeutics evaluated TG-1101 in multiple Phase I and Phase II studies.
- 27. Based on the data collected, and since in oncology settings, anti-CD20 is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as

opposed to single agent usage, the Company has developed multiple combination trials for TG-1101.

- 28. Notably, in September 2014 the Company reached an agreement with the FDA regarding a SPA on the design, endpoints and statistical analysis approach of a Phase III trial for TG-1101 in combination with ibrutinib, a drug already approved by the FDA, for the treatment of CLL in patients with high risk cytogenetics.
- 29. FDA regulations define a SPA as an agreement indicating concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design (*e.g.*, entry criteria, dose selection, endpoints, and planned analyses). These elements are critical to ensuring that the trial conducted under the protocol has the potential to support a future application's ability to meet regulatory requirements for approval. However, a SPA agreement does not indicate FDA concurrence on every protocol detail.
- 30. On December 9, 2014, TG Therapeutics announced the launch of "GENUINE," its phase III trial pursuant to the SPA. At that time, GENUINE was designed as a randomized controlled clinical trial, with patients receiving either TG-1101 plus ibrutinib or ibrutinib alone. The trial was to enroll approximately 330 patients, and consisted of two parts:
  - The Overall Response Rate ("ORR") data from the trial to assess the first 200 patients and as the basis for submission of a Biologics License Application (BLA) for accelerated approval for TG-1101, and
  - The progression free survival ("PFS") assessment for all 330 patients, which is designed to support full approval, and constitutes the primary endpoint.
- 31. TG Therapeutics continued its GENUINE Phase III trial in 2015 and 2016, even though the Company was rapidly facing patient enrollment issues, leading the Company eventually, on October 13, 2016, to eliminate the primary endpoint of the study, losing the SPA

negotiated with the FDA, cutting planned enrollment to 120 patients and highly increasing the risk of disapproval of the drug by FDA.

#### B. Material Misstatements and Omissions during the Class Period

32. On September 15, 2014, TG Therapeutics issued a press release about the SPA successfully negotiated with the FDA ("September 2014 Press Release"). The Company also attached the press release to a Form 8-K filed with the SEC. In the September 14 Press Release, Defendants touted the SPA and assured investors that the trial data would serve as the basis to submit a Biologics License Application ("BLA") "for accelerated approval" to the FDA and for full approval of the combination treatment:

TG Therapeutics, Inc. (Nasdaq:TGTX) announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for TG-1101 (ublituximab), its glycoengineered anti-CD20 monoclonal antibody, in combination with Imbruvica® (ibrutinib) for the treatment of Chronic Lymphocytic Leukemia (CLL) in patients with high risk cytogenetics. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval.

Full details of the Phase 3 clinical trial will be released at the launch of the study, which is expected to occur before the end of the year. In this randomized controlled trial, patients will receive either TG-1101 plus ibrutinib or ibrutinib alone. The trial will enroll approximately 330 patients, with approximately the first two-thirds of the patients included in the ORR assessment. As per the SPA, the Company plans to use the ORR data from the trial as the basis for submission of a Biologics License Application (BLA) for accelerated approval for TG-1101. All patients will then be followed for PFS assessment, which is designed to support full approval.

[...]

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of

treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

(Emphasis Added).

33. On December 9, 2014, the Company issued a press release ("December 2014 Press Release"), falsely assuring investors that the Phase III GENUINE trial would be a success, stating, in relevant part:

We continue to be impressed with the clinical activity and safety profile of ublituximab in combination with ibrutinib, especially in the high-risk CLL patient group which we will be evaluating in the upcoming Phase 3 trial. This data not only shows ublituximab can be safely combined with ibrutinib, but also can induce rapid and deeper responses compared to prior trials of ibrutinib alone. I am very excited, along with the team of investigators at US Oncology, to lead the upcoming Phase 3 trial and believe it will be an attractive protocol with great interest from patients for this study."

(Emphasis Added).

34. Moreover, Defendant Weiss further touted the Phase III trial:

We are thrilled by the data presented today by Dr. Sharman and colleagues which further supports our previously announced Phase 3 strategy for TG-1101. The high-risk CLL patient group, which achieved a 95% ORR, is the same patient population we will be studying in our randomized Phase 3 trial which utilizes ORR as a primary endpoint to support accelerated approval. [...] These results, coupled with a favorable safety profile, which does not appear to differ significantly from that of single agent ibrutinib, continues to support our belief that TG-1101 plus ibrutinib is an attractive treatment option for patients with relapsed refractory CLL and MCL. We thank Dr. Sharman and all the investigators from this Phase 2 trial, and look forward to the imminent launch of our Phase 3 trial of TG-1101 with ibrutinib.

(Emphasis Added).

35. On March 12, 2015, during a conference call with investors regarding the Company's fourth quarter 2014 financial results, Defendant Weiss stated in pertinent part:

As per the SPA, if positive the company plans to file the overall response data from the trial to support accelerated approval for TG-1101. All patients will then be followed for progression free survival or PFS, which is designed to support full approval of TG-1101. We are very excited about the prospects of this study and look forward to completing enrollment and reporting on the overall response endpoint in the second half of 2016.

(Emphasis Added).

36. On June 18, 2015, the Company issued a press release ("June 2015 Press Release"), in which Defendants ensured investors that the GENUINE Phase III trial was performing well and described it as a "best-in-class treatment":

We continue to be pleased with the performance of the combination of TG-1101 plus ibrutinib and continue to believe the combination represents best-in-class treatment patients for a relapsed/refractory CLL, especially in patients with high-risk disease, which is generally known to be chemotherapy resistant. We expect, if approved, TG-1101 will be the first chemo-free combination approved with ibrutinib for patients with relapsed/refractory CLL. The data presented today gives us additional confidence that the outcome of our Phase 3 GENUINE Study will be successful and we will be able to offer patients a novel chemo-free treatment option. We greatly appreciate the dedication to the program from our Study Chair Dr. Jeff Sharman and all the participating sites and physicians across the country that are participating in this important clinical trial.

(Emphasis Added).

37. On August 10, 2015 during a conference call with investors and analysts regarding the second quarter 2015 financial results, Defendant Weiss falsely claimed that patient enrollment in the GENUINE Phase III trial was on track and that the study "is supported by . . . compelling data":

[L]et me do a quick update on our ongoing GENUINE Phase 3 trial. During the quarter we were excited to announce that we now have over 120 sites open to enrollment into this Phase 3 clinical trial. **Driving enrollment into our GENUINE trial is our top priority and to already have so many sites on board is an incredible accomplishment.** From the design standpoint the GENUINE Phase 3 study is a randomized trial

where patients will receive either 1101 in combination with ibrutinib or ibrutinib alone. The population for this study is patients with high risk chronic lymphocytic leukemia or CLL, while **the primary endpoint of the study is progression free survival**.

Approximately the first few 100 patients of an expected total enrollment of approximately 330 patients will be assessed for overall response rate or ORR. If the ORR assessment is positive, as per our session protocol assessment or SPA, the company plans to use the overall response data as a basis for submission for accelerated approval for 1101. All patients will then be followed for PFS assessment, which is designed to support full approval. As mentioned in the past we hope to complete enrollment into the study and evaluate the overall response endpoint by the end of 2016. The study is supported by what we believe is very compelling data demonstrating the safety and activity of this regimen.

(Emphasis Added).

38. On March 7, 2016, the Company issued a press release ("March 2016 Press Release"), commenting on the Company's Fiscal Year 2015 results and the outcome of the GENUINE Phase III trial:

2015 was a transformational year for our Company as we launched our first registration study, the GENUINE Phase 3 study, and also obtained an SPA for our proprietary combination of TG-1101 and TGR-1202, the '1303' regimen, enabling our UNITY-CLL trial for patients with front-line and previously treated CLL. **During 2016 we will be focused on executing our ongoing Phase 3 clinical programs** as well as expanding our '1303' regimen into registration-directed trials for both diffuse large b-cell lymphoma and indolent lymphomas."

[...]

2015 Highlights:

- Commenced enrollment into the GENUINE Phase 3 clinical trial, which is **now open in over 150 sites throughout the US.** 

Key Objectives for 2016:

- Aggressively recruit into the GENUINE Phase 3 clinical trial.

(Emphasis Added).

39. On March 9, 2016, during an investor conference call on the fourth quarter and full-year 2015 financial results, Defendant Weiss reassured investors that the Phase III GENUINE trial was on track:

With 2015 spend building our trial site network, 2016 is a year of enrollment for us. We've been pleased by the early adapters into the GENUINE study, including several major academic centers as well as the few large community networks.

In the broader community, we found that testing for high risk CLL was not routinely done and since few front line patients have high risk features, many patients at the time of relapsed were not being receptive. We are in the process of launching a separate screening protocol that will enable sites to more easily screen all relapsing patients.

As expected, we're finding that about half of the patients that are screened, few have high risk features, which is consistent with our projections. Again, we believe the screening protocol that we're launching now will certainly streamline the process and accelerate enrollment.

With so many great sites on board, we believe we're nearing that key inflection point where these types of studies accelerate dramatically. When that occurs, we will be able to provide more clear guidance as to when the study will be completed, but until then we're continuing to target the end of year to complete enrollment with data in early '17.

(Emphasis added).

- 40. On May 10, 2016, TG Therapeutics issued a press release ("May 2016 Press Release) reaffirming the 2016 milestones for the GENUINE Phase II trial, including the continuation to "aggressively" recruit into the trial.
- 41. During an August 8, 2016 conference call with investors, Defendant Weiss continued to reassure investors that, despite slower than expected enrollment in the GENUINE Phase III trial, Defendants were fixing the issue and that they "still believe that GENUINE's goal of improving on ibrutinib therapy represents an important treatment goal. There is no question that ibrutinib is a very good drug, but few if any patients are cured with single agent ibrutinib." (Emphasis added).

42. The statements in paragraph 32-41, above were materially false and misleading when made because, contrary to Defendants' representations, TG Therapeutics had failed to implement a proper screening protocol in the GENUINE enrolling sites, was not enrolling patients at the required rate for the study to be completed on time, the trial would never get 330 enrolled patients, and PFS was not an achievable endpoint.

#### C. The Truth Emerges

43. On October 13, 2016, the Company issued a press release ("October 2016 Press Release"), announcing that it had filed with the FDA an amended protocol for the GENUINE Phase 3 trial GENUINE Phase III trial. The Company also attached the press release to a Form 8-K filed with the SEC. The press release stated in pertinent part:

TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that it has filed with the FDA an amended protocol for the GENUINE Phase 3 trial. Prior to the amendments, the GENUINE study consisted of two parts:

- Part I to evaluate the effect of the addition of TG-1101 to ibrutinib on overall response rate (ORR) in approximately the first 200 patients enrolled, to support a filing for accelerated approval of TG-1101; and
- Part II to evaluate the effect of the addition of TG-1101 to ibrutinib on progression-free survival (PFS) in all study patients (approximately 330), to support a filing for full approval of TG-1101.

#### The amended protocol contains the following substantive changes:

- Part II of the study has been eliminated, and accordingly, the study's sole primary endpoint will be ORR as originally contemplated in Part I; and
- Target enrollment has been reduced to approximately 120 randomized patients.

At the new study size, the study is 90% powered to show a statistically significant improvement in ORR, with the minimal detectable difference of approximately 20% (absolute difference between the arms). Additionally, patients will be followed until progression, but the study will no longer be powered for PFS.

The Company expects that it will complete enrollment in the revised trial by year end 2016, and will have topline data available in the first half of 2017. If the results of the study are positive, the Company plans to request a pre-BLA meeting to discuss the data and a filing strategy with the FDA. The Company has communicated with the FDA regarding its intention to file a BLA for accelerated approval if the results are positive

and the FDA has agreed that a pre-BLA meeting can be requested based on ORR data from the GENUINE study. Assuming a positive outcome of a pre-BLA meeting, targeted to occur in the fourth quarter of 2017, the Company believes it could file a BLA in the first half of 2018.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "Today's announcement marks an important milestone for the Company. Given the GENUINE enrollment challenges we've faced to date, we are very excited to accelerate the trial to a rapid conclusion, while also maintaining the ability to potentially file the data for accelerated approval. The GENUINE study, as amended, remains a robust, randomized clinical trial, which we believe, if positive, could support accelerated approval for patients with relapsed/refractory high-risk CLL. Moreover, we believe the amended study and revised regulatory strategy is consistent with the recent accelerated approvals for novel agents in CLL, which notably were not pursuant to an SPA but occurred after the finding of positive ORR results. Importantly, with completion of enrollment now expected by year end, we and our clinical trial sites can focus our resources on completing our UNITY-CLL Phase 3 trial as quickly as possible. Early enrollment in UNITY-CLL is very encouraging and we anticipate that study will be fully enrolled before filing a BLA for the GENUINE study. UNITY-CLL remains unchanged and unaffected by the amendments to the GENUINE study, and if positive, could support full approval for both TG-1101 and TGR-1202 based on its primary endpoint of PFS." Mr. Weiss continued, "We have greatly appreciated all of the guidance and counsel from the FDA in designing our clinical programs and we look forward to continuing our collaborative working relationship as we accelerate toward the conclusion of enrollment into the GENUINE study this year and ORR data in the first half of 2017."

(Emphasis Added).

44. Also on October 13, 2016, *TheStreet* published an article addressing the Company's October 2016 Press Release ("*TheStreet* October 13, 2016"). The article stated in pertinent part:

TG Therapeutics (TGTX) has long suffered from a management credibility problem. Thursday, CEO Mike Weiss tried to spin as positive a major revision to a pivotal phase III study of its anti-CD20 monoclonal antibody ublituximab in patients with relapsed/refractory, high risk chronic lymphocytic leukemia.

"Today's announcement marks an important milestone for the Company," said Weiss in the TG Therapeutics press release. "Given the GENUINE [phase III] enrollment challenges we've faced to date, we are very excited to accelerate the trial to a rapid conclusion, while also maintaining the ability to potentially file the data for accelerated approval."

Sure, if you define milestone as blowing up a Special Protocol Assessment reached with the FDA, cutting planned enrollment by one third, eliminating important

efficacy endpoints and generally loading up the study and the company's regulatory strategy with way more risk. Excellent!

TG Therapeutics is down 15% to \$7.05.

(Emphasis Added).

- 45. The same day, on a conference call to discuss the amendments to the GENUINE Phase III trial, CEO Weiss revealed that 330 patients was a number that was highly overpowered, and that 120 patients would be sufficient to achieve FDA approval, consistent with prior discussions between the Company and the FDA.
- 46. On the announcement, the Company's share price declined from \$8.25 per share on October 12, 2016, to close at \$6.01 per share on October 17, 2016, a drop of approximately 27%.

#### **ADDITIONAL SCIENTER ALLEGATIONS**

As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding TG Therapeutics, their control over, and/or receipt and/or modification of TG Therapeutics' allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning TG Therapeutics, participated in the fraudulent scheme alleged herein.

#### LOSS CAUSATION AND ECONOMIC LOSS

48. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the Company's stock price,

and operated as a fraud or deceit on acquirers of the Company's securities. As detailed above, when the truth about TG Therapeutics' misconduct and its lack of operational and financial controls was revealed, the value of the Company's securities declined precipitously as the prior artificial inflation no longer propped up its stock price. The decline in TG Therapeutics' share price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the common stock price decline negates any inference that the loss suffered by Plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the Company's stock price and the subsequent significant decline in the value of the Company's share, price when Defendants' prior misrepresentations and other fraudulent conduct was revealed.

49. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of TG Therapeutics' business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing TG Therapeutics' securities to be artificially inflated. Plaintiff and other Class members purchased TG Therapeutics' securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

#### PRESUMPTION OF RELIANCE; FRAUD-ON-THE-MARKET

- 50. At all relevant times, the market for TG Therapeutics securities was an efficient market for the following reasons, among others:
  - (a) TG Therapeutics securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market;
  - (b) During the Class Period, TG Therapeutics securities were actively traded, demonstrating a strong presumption of an efficient market;
  - (c) As a regulated issuer, TG Therapeutics filed with the SEC periodic public reports during the Class Period;
  - (d) TG Therapeutics regularly communicated with public investors via established market communication mechanisms;
  - (e) TG Therapeutics was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and
  - (f) Unexpected material news about TG Therapeutics was rapidly reflected in and incorporated into the Company's stock price during the Class Period.
- 51. As a result of the foregoing, the market for TG Therapeutics securities promptly digested current information regarding TG Therapeutics from all publicly available sources and reflected such information in TG Therapeutics' stock price. Under these circumstances, all purchasers of TG Therapeutics securities during the Class Period suffered similar injury through their purchase of TG Therapeutics' securities at artificially inflated prices, and a presumption of reliance applies.
- 52. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant

to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Here, the facts withheld are material because an investor would have considered the Company's true net losses and adequacy of internal controls over financial reporting when deciding whether to purchase and/or sell stock in TG Therapeutics.

# NO SAFE HARBOR; INAPPLICABILITY OF BESPEAKS CAUTION DOCTRINE

- 53. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.
- 54. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.
- 55. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of TG Therapeutics who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by the defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

#### **CLASS ACTION ALLEGATIONS**

- 56. Plaintiffs bring this action on behalf of all individuals and entities who purchased or otherwise acquired TG Therapeutics securities on the public market during the Class Period, and were damaged, excluding the Company, the Defendants and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest (the "Class").
- 57. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, TG Therapeutics securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by TG Therapeutics or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of August 1, 2016, TG Therapeutics had 54,456,623 outstanding shares of common stock. Upon information and belief, these shares are held by individuals located geographically throughout the country and possibly the world. Joinder would be highly impracticable.
- 58. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by the defendants' respective wrongful conduct in violation of the federal laws complained of herein.
- 59. Plaintiffs have and will continue to fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities

litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

- 60. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - (a) whether the federal securities laws were violated by the defendants' respective acts as alleged herein;
  - (b) whether the defendants acted knowingly or with deliberate recklessness in issuing false and misleading financial statements;
  - (c) whether the price of TG Therapeutics securities during the Class Period was artificially inflated because of the defendants' conduct complained of herein; and
  - (d) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages?
- 61. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

# <u>COUNT I</u> <u>Violation of Section 10(b) and Rule 10b-5 Against All Defendants</u>

- 62. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 63. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (2) cause Plaintiff and

other members of the Class to purchase TG Therapeutics securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

- 64. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for TG Therapeutics securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.
- 65. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of TG Therapeutics as specified herein.
- 66. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of TG Therapeutics' value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about TG Therapeutics and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that

operated as a fraud and deceit upon the purchasers of TG Therapeutics securities during the Class Period.

- 67. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents at the Company during the Class Period and members of the Company's management team or had control thereof; (2) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's financial condition; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendant and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (4) each Individual Defendant was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.
- 68. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing TG Therapeutics' operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's financial condition throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by

deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

- 69. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of TG Therapeutics' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of TG Therapeutics' publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired TG Therapeutics' securities during the Class Period at artificially high prices and were or will be damaged thereby.
- 70. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding TG Therapeutics' financial results, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their TG Therapeutics securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.
- 71. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

- 72. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.
- 73. This action was filed within two years of discovery of the fraud and within five years of the Plaintiff's purchase of securities giving rise to the cause of action.

## <u>COUNT II</u> The Individual Defendants Violated Section 20(a) of the Exchange Act

- 74. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 75. The Individual Defendants acted as controlling persons of TG Therapeutics within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.
- 76. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to

control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

- 77. As set forth above, TG Therapeutics, the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.
- 78. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.
- 79. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

- (a) Determining that this action is a proper class action, certifying Plaintiff as class representative under Federal Rule of Civil Procedure 23 and Plaintiff's counsel as class counsel;
- (b) Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of the defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;
- (d) Granting extraordinary equitable and/or injunctive relief as permitted by law;

and

(e) Such other and further relief as the Court may deem just and proper.

### JURY TRIAL DEMANDED

Plaintiff hereby demands a jury trial.

Dated: January 6, 2017 Respectfully submitted,

#### LEVI & KORSINSKY LLP

#### /s/Shannon L. Hopkins

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